INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P39PC00	**FOR FURTHER ACTION** See Form PCT/IPEA/416	
International application No. PCT/SE2003/001477	International filing date *(day/month/year)* 22-09-2003	Priority date *(day/month/year)*
International Patent Classification (IPC) or national classification and IPC **See Supplemental Box**		
Applicant **Sectra Imtec AB et al**		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of **5** sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

   a. ☒ *(sent to the applicant and to the International Bureau)* a total of **5** sheets, as follows:

       ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

       ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s))

       _____ , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

   ☒ Box No. I   Basis of the report

   ☐ Box No. II   Priority

   ☐ Box No. III   Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

   ☐ Box No. IV   Lack of unity of invention

   ☒ Box No. V   Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

   ☐ Box No. VI   Certain documents cited

   ☐ Box No. VII   Certain defects in the international application

   ☐ Box No. VIII   Certain observations on the international application

Date of submission of the demand 18-03-2005	Date of completion of this report 21-12-2005
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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Cover sheet

INTERNATIONAL PATENT CLASSIFICATION (IPC):

A61B 6/04 (2006.01)
G06T 7/00 (2006.01)

Box No. I	Basis of the report

1. With regard to the **language**, this report is based on:

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into _____ ,
   which is the language of a translation furnished for the purposes of:

   ☐ international search (Rules 12.3(a) and 23.1(b))

   ☐ publication of the international application (Rule 12.4(a))

   ☐ international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

   ☐ the international application as originally filed/furnished

   ☒ the description:

   pages **1-15** _____ as originally filed/furnished

   pages* _____ received by this Authority on _____

   pages* _____ received by this Authority on _____

   ☒ the claims:

   pages _____ as originally filed/furnished

   pages* _____ as amended (together with any statement) under Article 19

   pages* **1-5** _____ received by this Authority on **04.08.2005**

   pages* _____ received by this Authority on _____

   ☒ the drawings:

   pages **1/5-5/5** _____ as originally filed/furnished

   pages* _____ received by this Authority on _____

   pages* _____ received by this Authority on _____

   ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

   ☐ the description, pages _____

   ☐ the claims, Nos. _____

   ☐ the drawings, sheets/figs _____

   ☐ the sequence listing *(specify)*: _____

   ☐ any table(s) related to the sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

   ☐ the description, pages _____

   ☐ the claims, Nos. _____

   ☐ the drawings, sheets/figs _____

   ☐ the sequence listing *(specify)*: _____

   ☐ any table(s) related to the sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-28	YES
	Claims		NO
Inventive step (IS)	Claims	1-28	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-28	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

The invention relates to a method and a system for assuring sufficient image quality in medical imaging. According to the invention, an object is imaged and the image is analysed in realtime by a computerized algorithm in order to identify predefined features (landmarks) of the object in the image. Based on image processing measurements on the identified landmarks, computerized image processing and predefined criteria produces a real-time positioning quality assessment result, the result being presented to an operator. Using the result the operator can determine if an image has to be retaken or not. One main aim of the invention is to minimize the time needed for the positioning of a patient in the imaging process. The invention is applied in the field of mammographic imaging.

Documents cited in the International Search Report:

D1: US 5423316 A1
D2: US 5913822 A1
D3: WO 9518561 A2

D1 describes a method and an apparatus for automatic (computerized) identification of anatomical landmarks in images obtained from a medical imaging system. According to the method, a patient is initially positioned relative an imaging camera, one or more images are generated and analysed by a computerized algorithm, through which anatomical landmarks of interest are identified. By superimposing plots of the landmarks on an image presented on a display, it is possible to determine if the patient is properly positioned relative the camera, i.e. if the image comprises the regions of interest.

.../...

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box V

If any landmarks are missing, repositioning of the patient or camera is performed manually or automatically.

D2 describes a method of optimization of image parameters in nuclear medicine in which the image analysis is made in real-time and where a decision is made whether the patient is properly positioned relative an imaging device.

In D3, a mammographic imaging system is shown, in which breast features, such as borders or other landmarks are identified and displayed, in order to produce computer enhanced mammograms.

The invention differs from the cited prior-art by not only identifying the landmarks but also performing a computerized image processing to determine the image quality and the positioning quality, using at least one predetermined criteria.

The invention therefore has novelty.

Taking the above differences into consideration, it is not considered to be an obvious step for a skilled person to use the teachings of D1-D3, alone or combined, to attain a solution according to the invention as claimed.

The invention therefore show inventive step.

The invention is also considered to have industrial applicability.

CLAIMS

1. A method for mammographic image quality assurance comprising computerized processing of at least one digital mammographic image to identify landmark areas of the breast, **characterized in that** said method further comprises:

- computerized processing based on image processing measurements on identified landmark areas of the breast together with at least one associated criterion for assessing image positioning quality to produce an automated real-time positioning quality assessment result; and

- communicating said positioning quality assessment result on a user interface to enable a real-time decision by a technologist whether to retake said at least one mammographic image with improved positioning.

2. The method according to claim 1, wherein said at least one criterion for assessing image positioning quality includes a set of threshold values.

3. The method according to claim 1, further comprising the step of retaking said at least one mammographic image with improved positioning if the quality assessment result indicates that the image is inadequately positioned.

4. The method according to claim 3, comprising multiple retakes of inadequately positioned images, continuously updating which image or set of images among said multiple retakes that is considered most adequate.

5. The method according to claim 1, wherein said positioning quality assessment result further comprises visual indication of inadequately positioned areas of the breast on a graphical user interface.

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6. The method according to claim 1, wherein said positioning quality assessment result includes a number of user-configurable parameters, thus allowing a selectable level of detail in communicating the result.

5   7. The method according to claim 1, wherein said positioning quality assessment result includes at least one of a visual part and a statistics part.

8. The method according to claim 1, wherein at least one threshold for poor contra good image positioning in said processing is configurable via a user interface.

10   9. The method according to claim 1, wherein said at least one mammographic examination comprises several projections.

10. The method according to claim 1, wherein said at least one mammographic

15   examination comprises at least one of a CC (Cranio-caudal) projection, an MLO (Medio-lateral oblique) projection, an LM (Latero-medial) projection and an ML (Medio-lateral) projection.

11. The method according to claim 1, wherein said method is applied in

20   mammographic screening.

12. A system for mammographic image quality assurance, wherein said system comprises means for computerized processing of at least one digital mammographic image to identify landmark areas of the breast, **characterized in that** said system

25   further comprises:
         - means for computerized processing based on image processing measurements on identified landmark areas of the breast together with at least one associated criterion for assessing image positioning quality to produce an automated real-time positioning quality assessment result; and

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    -    means for communicating said positioning quality assessment result on a user interface to enable a real-time decision by a technologist whether to retake said at least one mammographic image with improved positioning.

13. The system according to claim 12, wherein said at least one criterion for assessing image positioning quality includes a set of threshold values.

14. The system according to claim 12, further comprising means for retaking said at least one mammographic image with improved positioning if the quality assessment result indicates that the image is inadequately positioned.

15. The system according to claim 14, comprising means for multiple retakes of inadequately positioned images, and means for updating which image or set of images among said multiple retakes that is considered most adequate.

16. The system according to claim 12, wherein said positioning quality assessment result includes visual indication of inadequately positioned parts of the breast on a graphical user interface.

17. The system according to claim 12, further comprising means for user-configuration of at least one threshold for poor contra good image positioning in said processing.

18. The system according to claim 12, wherein said system is part of a mammographic screening system.

19. A digital mammography system comprising:
    -    means for generating at least one digital mammographic image of a patient;

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- means for computerized processing of at least one digital mammographic image to identify landmark areas of the breast,

characterized in that said system further comprises:

- means for computerized processing based on image processing measurements on identified landmark areas of the breast together with at least one associated criterion for assessing image positioning quality to produce an automated real-time positioning quality assessment result;

- means for determining, based on the positioning quality assessment result, whether the image positioning quality of said at least one mammographic image is sufficient; and

- means for retaking, if the image positioning quality is insufficient, said at least one mammographic image with improved positioning.

20. The digital mammography system according to claim 19, further comprising means for communicating said positioning quality assessment result to a technologist.

21. The digital mammography system according to claim 19, wherein said at least one criterion for assessing image positioning quality includes a set of threshold values.

22. A computer program product for performing, when running on a computer, mammographic image quality assessment, said computer program product comprising program means for computerized processing of at least one digital mammographic image to identify landmark areas of the breast, **characterized in that** said computer program product further comprises:

- program means for computerized processing based on image processing measurements on identified landmark areas of the breast together with at least one associated criterion for assessing image positioning quality to produce an automated real-time positioning quality assessment result;

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- program means for communicating said positioning quality assessment result on a user interface to enable a real-time decision whether to retake said at least one mammographic image with improved positioning while the patient is still present.

5   23. The computer program product according to claim 22, wherein said at least one criterion for assessing image positioning quality includes a set of threshold values.

24. The computer program product according to claim 22, wherein said program means for communicating said positioning quality assessment result includes program
10   means for enabling visual indication of inadequately positioned parts of the breast on a graphical user interface.

25. The computer program product according to claim 22, further comprising program means for user-configuration of at least one threshold for poor contra good
15   image positioning in said processing.

26. The computer program product according to claim 22, wherein said computer program product is implemented in an image acquisition workstation of a digital mammography system.

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27. The computer program product according to claim 26, wherein said computer program product is implemented for integrated operation with existing software in said workstation.

25   28. The computer program product according to claim 22, wherein said computer program product is carried on a computer-readable medium.

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